SEP 30 2005

K052464

510(k) Summary – Tina-Quant® Hemoglobin A1c Gen.2

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Theresa M. Ambrose

Date prepared: Sept 7, 2005

Device Name

Proprietary name: Tina-Quant® Hemoglobin A1c Gen.2 test

Common name: Hemoglobin A1c test

Classification name: Glycosylated hemoglobin assay

Device Description

With the Tina-Quant Hemoglobin A1c Gen.2 test system, the anticoagulated whole blood specimen is hemolyzed prior to determination of HbA1c by an turbidimetric inhibition immunoassay (TINIA). Liberated hemoglobin (Hb) in the hemolyzed sample is converted to a derivative having a characteristic absorption spectrum and measured bichromatically. The instrument calculates the % HbA1c from the HbA1c/ Hb ratio according to a user selected protocol.

Intended use

The Tina-Quant Hemoglobin A1c Gen.2 test is an in vitro diagnostic reagent system intended for the quantitative determination of percent hemoglobin A1c in whole blood.
HbA1c results are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Predicate Device

We claim substantial equivalence to the Tina-Quant ® Hemoglobin cleared as K934070.

Substantial equivalency – Similarities

The table below indicates the similarities between the modified Tina-Quant ® Hemoglobin A1c Gen.2 test and its predicate device (original Tina-Quant ® Hemoglobin, K934070).

Feature	Predicate device: original Tina-Quant HbA1c (K934070)	Modified device: Tina-Quant HbA1c Gen.2
General		
Intended Use/ Indications for Use	For the quantitative determination of hemoglobin A1c in whole blood. From summary: Measurements are useful to provide an indication of glycemic control in patients with diabetes mellitus.	The Tina-Quant Hemoglobin A1c Gen.2 test is an in vitro diagnostic reagent system intended for the quantitative determination of percent hemoglobin A1c in whole blood. HbA1c results are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus
Specimen type	Capillary blood;EDTA or heparinized whole blood.	Same
Test principle		
Determination of HbA1c	Turbidimetric immunoinhibition (TINIA). Antigen-antibody complexes are formed and excess Ab aggregate with polyhapten to form insoluble complexes.	Same
Determination of Hb	Bichromatic photometric determination after conversion to a colored derivative.	Same.
Calculation of % HbA1c	% HbA1c is calculated automatically by instrument according to user-selected protocol	Same
Reagent information		
Hemolyzing reagent: sample ratio	1:100	Same
Antibody	Polyclonal anti-HbA1c from sheep blood	Same antibody.
Calibrator	Hemolysate derived from human blood and sheep blood; TTAB detergent; stabilizer.	Same
Quality control	Precinorm HbA1c Precipath HbA1c	Same
Performance characteristics		

Specificity	No cross-reactivity with HbAo, HbA1a, HbA1b, acetylated hemoglobin, carbamylated hemoglobin, glycated albumin, labile HbA1c and HbA1d and an acetaldehyde hemoglobin adduct.	Stability claims transferred from predicate device due to use of same antibody and similar reagent: sample ration.

Substantial equivalency – Differences

The table below indicates the differences between the modified Tina-Quant ® Hemoglobin A1c Gen.2 test and its predicate device (original Tina-Quant ® Hemoglobin, K934070).

Feature	Predicate device: original Tina-Quant HbA1c (K934070)	Modified device: Tina-Quant HbA1c Gen.2
General		
Pretreatment	Manual pretreatment with hemolyzing reagent	Two options for pretreatment: Hemolysate application: same (Manual pretreatment with hemolyzing reagent) Whole blood application: automated on-board sample pretreatment with hemolyzing reagent
Instruments	Automated analyzers including Hitachi family	Integra 800
Test principle		
Determination of Hb	Occurs in separate channel with separate reagent.	Hb is measured in same channel during preincubation phase of HbA1c determination (sample + R1). No separate reagent or channel needed.
Reagent information		
R1	Buffer: 50 mM MES, pH6.2 Antibody; stabilizers	Buffer: 25 mM MES/ 15 mM TRIS pH 6.2 Antibody; stabilizers
R2	Buffer: 50 mM MES, pH 6.2; Polyhapten modified with aminodextran AD50; concentration > 20 ug/mL Stabilizers	Buffer: 25 mM MES/15mM Tris, ph 6.2; Polyhapten modified with aminodextran AD500; concentration > 8ug/mL; Stabilizers

Hemolyzing reagent	Contains 10 mM EDTA and TTAB detergent	Different concentrations used <u>Hemolysate application:</u> Uses separate hemolyzing reagent with 20 mM EDTA <u>Whole blood application:</u> Uses Hemolyzing reagent Gen.2 – fourfold increase in concentration
Hb reagent	Phosphate buffer 20 mM, pH 7.4; stabilizers	No separate reagent needed.
Calibrator	Provided with kit as lyophilisate in four levels.	Provided separately as single level; diluted on-board the analyzer.
Traceability	In-house reference materials	Standardized against approved IFCC reference method
Reagent stability	2-8 °C until expiration date opened: 4 weeks at 2-12 °C	2-8 °C until expiration date On-board: 28 days
[illegible]		
Precision	Within run: 3.8% @ 5.2 % HbA1c 4.0% @ 11.3% HbA1c Total: 5.8% @ 5.2 % HbA1c 5.6% @ 11.3% HbA1c	<u>Whole blood application:</u> Within run: 0.8 % @ 5.4% HbA1c 0.9% @ 10.2% HbA1c Between day: 1.3% @ 5.3% HbA1c 1.0% @ 10.3% HbA1c <u>Hemolysate application</u> Within run: 1.0 % @ 55% HbA1c 0.6% @ 10.6% HbA1c Between day: 1.0% @ 5.3% HbA1c 0.8% @ 10.7% HbA1c
Linearity	0.3 g/dL up to highest calibrator for HbA1c. 9-24 g/dL Hb (before dilution)	0.3-2.6 g/dL HbA1c 4-35 g/dL Hb (before dilution) (Based on highest calibrator value)
Lower detection limit	0.3 g/dL HbA1c	0.02 g/dL HbA1c 0.09 g/dL Hb

Endogenous interferences	No interference from Acetylsalicylic acid; Gamma globulin; Rheumatoid factor or ascorbic acid Lipemia up to 17.5 mg/dL Lipemia (intralipid) up to 1230 mg/dL	<u>Whole blood application:</u> No significant interference from: Icterus Lipemia: up to 800 mg/dL Intralipid Rheumatoid factor: up to 750 IU/mL Glycemia: up to 1000 mg/dL glucose
Expected values	4.3% - 5.8% HbA1c Based on 1993 study with in-house standardization	2.9-4.2% HbA1c Based on study done with IFCC standardization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 30 2005

Ms. Theresa Ambrose
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Indianapolis, IN 46250

Re: k052464
Trade/Device Name: Tina-Quant® Hemoglobin A1c Gen.2 Test
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: September 07, 2005
Received: September 08, 2005

Dear Ms. Ambrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052464

Device Name: **Tina-Quant® Hemoglobin A1c Gen.II**

Indications For Use:

The Tina-Quant Hemoglobin A1c Gen.2 test is an in vitro diagnostic reagent system intended for the quantitative determination of percent hemoglobin A1c in whole blood.
HbA1c results are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052464